REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Summary of the Amendments to the Claims

Upon entry of this Amendment, claims 1-46 will remain pending in the application, with claims 1-43 under active consideration as claims 44-46 have been withdrawn as drawn to non-elected subject matter. A detailed listing of all claims that are, or were, in the application, irrespective of whether a particular claim remains under examination in the application, is presented, beginning on page 2 of this paper under "Listing of Claims," with an appropriate defined status identifier.

Claim 1 has been amended to state that the composition comprises "at least about 5% water, based on the total weight of the composition." Exemplary support for this amendment can be found in the application at, for example, paragraph 30.

Because the foregoing amendment does not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in the Office Action

A. Claim Rejections – 35 U.S.C. § 102(b)

Claims 1-8, 12-22, 24-28, and 30-43 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 00/18374 ("the '374 application"). Applicants respectfully traverse this ground for rejection.

The co-owned '374 application, for "Controlled Release Nanoparticulate Compositions," is directed to compositions comprising an active agent having an effective average particle size of less than about 1 micron (e.g., 1000 nm), at least one surface stabilizer, and at least one rate controlling polymer, wherein the composition provides for

controlled release of the active agent for a time period ranging from about 2 to about 24 hours or longer. This does not teach or suggest the claimed invention.

1. The "Rate Controlling Polymer" of the '374 Application Does not Teach or Suggest the "Gel Forming Substance" of the Claimed Invention

The claimed invention is directed to gelatin compositions comprising an active agent having an effective particle size of less than about 2000 nm, a surface stabilizer, and a gel forming substance. The "rate controlling polymer" of the '374 application is not synonymous, nor does it suggest, the "gel forming substance" of the claimed invention.

Specifically, rate controlling polymers of the '374 application function to slow the release rate of the drug from the composition such that the drug is released over a time period from about 2 to about 24 hours: "Rate-controlling polymers include hydrophilic polymers, hydrophobic polymers, and mixtures of hydrophobic and hydrophilic polymers that are capable of retarding the release of a drug compound from a composition or dosage form of the present invention." See the '374 application at pages 13-14. This dosage form is unique, as nanoparticulate active agents are known to have a rapid rate of release.

In contrast to the '374 application, the gel forming substance of the claimed invention does not *slow* the rate of release of the active agent. Rather, as taught in the specification, the gelatin dosage form of the invention "disperse[s] and essentially melt[s] upon administration." Paragraph 31 of the application.

2. The Compositions of the Invention Require the Presence of "Excess Water" in a Solid or Semi-Solid State, which, in Contrast to the '374 Application, Results in Fast Release of the Active Agent

In contrast to the compositions of the '374 application, which exhibit controlled release, the compositions of the invention exhibit fast, immediate release of the component active agent. Specifically, Applicants teach that "[t]he solid or semi-solid nanoparticulate active agent gelatin dosage forms of the invention exhibit gelation sufficient to retain excess water in the solid or semi-solid active agent dosage form, which provides for rapid redispersion of the active agent." *See* paragraph 46 of the application.

Prior to the present invention, while gelatin dosage forms were desirable, there was an inherent conflict in desiring more water in the dosage form to increase redispersion of the active agent, and knowing that the presence of a significant percentage of water can result in degradation of the active agent to be delivered. It was unexpectedly discovered that the presence of water does not destabilize or degrade the nanoparticulate active agent in the dosage forms of the invention. *See* paragraph 30 of the application.

The presence of excess water in a nanoparticulate dosage form is not taught or suggested by the '374 application. This is because it is the presence of excess water which "provide[s] for redispersability of the nanoparticulate active agent particles upon administration." *See* paragraph 31 of the application. Such rapid redispersion is contrary to the goal of the '374 application; e.g., controlled release of the component active agent.

3. No Motivation to Modify the Teachings of the '374 Application to Obtain the Claimed Invention

The '374 application is directed to *controlled release dosage forms.* Because the gel forming substance of the claimed compositions results in compositions comprising "excess water", and thereby rapid redispersion of the component active agent, the claimed compositions are *immediate release dosage forms,* and not controlled release dosage forms. There is no motivation in the art to attempt to modify the teaching of the '374 application to obtain the claimed compositions, which require the presence of excess water which consequently produces rapid release of the component active agent. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

B. Claim Rejections – 35 U.S.C. § 102(a)

Claims 1-4, 6-8, 12-22, 24-28, and 30-43 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by US Patent No. 6,316,029 ("the '029 patent"). Applicants respectfully traverse this ground for rejection.

The '029 patent, for "Rapidly Disintegrating Solid Oral Dosage Form," is directed to fast melt dosage forms comprising a nanoparticulate active agent having an effective average

particle size of less than about 2 microns, at least one surface stabilizer, and at least one pharmaceutically acceptable water-soluble or water-dispersible excipient. This reference does not teach or suggest compositions comprising a gel forming substance that result in compositions comprising "an excess" of water.

Specifically, the compositions of the '029 patent comprise solid dosage forms made by tableting a powder made, for example, by spray drying, lyophilization, granulation, or tableting. *See e.g.*, cols. 10-11 of the '029 patent. Thus, the compositions of the '029 patent require *removal* of water from a dosage form. This is also demonstrated by the examples of the '029 patent, which teach fast melt dosage forms comprising "compound A, HPC-SL [hydroxypropyl cellulose], SLS [sodium lauryl sulfate], fructose, and sorbitol" (see Table 1, col. 12 of the '029 patent). *Water is not a component of the tablet.* Similarly, all of the exemplary tablet dosage forms given in the examples lack water as a component, which is consistent with the teaching of the '029 patent directed to dry, fast melt dosage forms.

In contrast to the '029 patent, the claimed invention is directed to dosage forms that retain excess water, *e.g.,* at least about 5%, by weight, of the claimed composition is water. This type of dosage form is not taught or suggested by the '029 patent. The retention of excess water is illustrated in the examples of application. In Example 1 the manufacture of a nanoparticulate gelatin formulation of Compound A is described. Essentially, a nanoparticulate dispersion of Compound A, comprising Compound A, a surface stabilizer, and water, was mixed into a molten mixture of 20% gelatin:80% water, resulting in a dispersion comprising 77.6% water. This dispersion was subsequently homogenized, dispensed into a mold, and refrigerated until formed (specification at paragraphs 0143-0148).

Therefore, the '029 patent does not teach or suggest each and every element of the claimed invention and, accordingly, the reference does not anticipate the claimed invention. Withdrawal of this ground for rejection is respectfully requested.

III. Conclusion

The present application is now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 7, 2006

By Michele M Simkin

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicants
Registration No. 34,717